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OFFICE OF THE UNDER SECRETARY OF DEFENSE

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Division of Dockets Management (HFA-305)
Attention: Ms. Jenny Butler
Food and Drug Administration
5630 Fishers Lane, RM. 1061
Rockville, MD 20852

RE: Docket No. 02N-0278, RIN 0910-AC41

Dear Ms. Butler:

The Department of Defense (DoD) appreciates the opportunity to provide comments to the interim rule on the implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. DoD fully supports the FDA charter to ensure public health protection of all US citizens from potential bioterrorism sources. However, unaccompanied baggage (UB) and household goods (HHG) shipments belonging to DoD personnel represent a very low level of risk. We do not believe it was the intent of Congress to impose these restrictions on individuals, especially DoD members who are not transferring ownership of their personal food items, but merely shipping them from one location to another. However, since these UB and HHG shipments were not specifically excluded we request an exemption to the provisions of 21 CFR Part 1, which will implement section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188), for DoD active duty military and civilian personnel UB and HHG shipments, and for food items shipped by DoD personnel through the Military Postal System (MPS).

Without an exemption, the new FDA rules will adversely impact both administratively and financially all DoD personnel and their families around the world. DoD sponsors approximately 125,000 UB and HHG shipments from overseas locations to the United States each year. The FDA should exercise its discretion in the implementation of rules that can be anticipated to cause financial hardship to DoD personnel and their families.

The proposed process is cumbersome and includes prior research of all food, food components and beverage manufacturers' names and codes, Bureau of Customs and Border Protection (CBP) identifiers, FDA product codes, estimated quantities, anticipated shipment arrival via land/air/water and prior import notification to FDA. The enormity of the research is far beyond the capability of military and civilian families and our contracted UB/HHG carriers. In addition, DoD personnel have no control over the timelines for their UB/HHG movements and, as such, cannot accurately provide the required prior date/time notification. The alternative to the proposed process will be to disallow food, food components and beverage importation to the United States. Disallowing importation would levy a significant financial hardship on our military members and DoD employees.

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In related activities, the President recently signed into law a DoD exemption to Chapter 449 of title 49 of the U.S. Code. This legislation exempts DoD charter flights from having to comply with the manifest requirements prescribed in 49 USC 44909. In addition, DoD requested and was granted an exemption to provisions of the Trade Act of 2002 requiring advanced collection of electronic manifest information for all DoD leased or chartered vessels and aircraft that are under DoD control and carry only DoD cargo.

In view of the actions outlined above and the impracticality and resultant hardship of implementing the rules for DoD personnel, we believe an exemption from provisions in section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188), for DoD active duty military and civilian personnel UB/HHG shipments, and for food items shipped through the MPS, is warranted. We would appreciate your favorable disposition of this issue. Should you need additional information or wish to discuss this matter further, my points of contacts are Mr. Adam Yearwood, 703 601-4461 ext. 102 or Mr. Fred Schutz ext. 103.

Sincerely,



Earl B. Boynton, Jr.
Assistant Deputy Under Secretary
(Transportation Policy)

cc: USTRANSCOM